DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 29, 2014

CareFusion Germany 234 GmbH
Mr. Elmar Niedermeyer
Leibnizstrasse 7
Hoechberg, Bavaria, Germany 97204

Re: K141936
Trade/Device Name: MicroLab MicroLoop
Regulation Number: 21 CFR 868.1840
Regulation Name: Diagnostic Spirometer
Regulatory Class: II
Product Code: BZG, DQA
Dated: 11/24/204
Received: 11/28/2014

Dear Mr. Niedermeyer,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin I. Keith -S

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

Device Name
MicroLab / MicroLoop

Indications for Use *(Describe)*

The MicroLab / MicroLoop spirometer is intended, for prescription use only, to measure the maximal volume and flow of air that can be moved in and out of a patient's lungs and for pulse oximetry measurements. The system is intended for use with pediatric (4 to 17 years) and adult (18 to 99 years) patients in hospitals, physician offices, laboratories and occupational health testing environments.

The optional Nonin IPOD® Integrated Pulse Oximetry Device is designed to measure pulse rate and oxygen saturation in adult patients. The sensor is designed for use on the fingers of patients weighing more than 30 kilograms, where the finger tissue is between 5 and 21 millimeters.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Deepika A. Lakhani -A
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for Dr. James Lee
Acting Branch Chief/ RPDB

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CareFusion

510(k) Summary

GENERAL INFORMATION

5.1 Type of Submission

Traditional 510(k) Submission

Submission date: 07/04/2014

5.2 Submitter

Name: CareFusion Germany 234 GmbH

Address: Leibnizstrasse 7
D-97204 Hoechberg
Germany

Contact person in Germany:
(Official Correspondent) **Elmar Niedermeyer**
Address: CareFusion Germany 234 GmbH
Leibnizstrasse 7, 97204 Hoechberg
Germany
Phone: +49 931 49 72 - 361
FAX: +49 931 49 72 - 62361
E-mail elmar.niedermeyer@carefusion.com

Contact person in the U.S.:
(U.S. Agent) **Donald Sherratt**
Address CareFusion
22745 Savi Ranch Parkway
Yorba Linda, CA 92887
Phone: 714-919-3349
Fax: 714-283-8420
E-mail: donald.sherratt@carefusion.com

5.3 Establishment Registration Number

9615102

5.4 Common Name or Classification Name

Spirometer, Diagnostic
(CFR 868.1840, Product Code BZG)
Oximeter
(CFR 870.2700, Product Code DQA)

5.5 Trade Name

MicroLab / MicroLoop

5.6 Device Classification

This is a Class II device

5.7 Classification Panel

73 Anesthesiology Part 868 Code BZG
74 Cardiovascular Part 870 Code DQA

5.8 Reason for Premarket Notification

- modification to existing MicroLab K031102
- SPIDA5 software will be superseded by SPCS (Spirometry PC Software)
- new housing & display, optional also without integrated printer available
- new option SpO_2 with Nonin Ipod® sensor

5.9 Legally predicate marketed devices

- Microlab Spirometer K031102 Code BZG
- SpiroPro K092324 Code BTY, DQA

5.10 Predicate Device Company

- CareFusion
- Viasys (now CareFusion)

5.11 Device Description

Description & function:

The MicroLab / MicroLoop is a mains/battery operated desktop spirometer. It has context sensitive help screens, accessed at the touch of a button, that explain its features and navigational aides, making it easy to use. The results may be uploaded to a PC using the optional "Spirometry PC" software and patient details may be downloaded to the MicroLab / MicroLoop. Using spirometry PC software (SPCS) and the MicroLab / MicroLoop, live blows can be performed with the PC directly controlling the operation of the MicroLab / MicroLoop. The results and graphs produced are displayed directly on the PC screen.

Stored data on the devices can be printed on an external printer using the USB cable supplied or uploaded to the PC. In addition the MicroLab is able to print the data on its integral thermal printer. Optional a Nonin Ipod® SpO2 sensor can be connected to the MicroLab / MicroLoop.

Scientific Concept:

The scientific concept which forms the basis of the MicroLab / MicroLoop is the CareFusion Digital Volume Transducer, a stable form of volume transducer, which measures expired air directly at B.T.P.S (Body Temperature and Pressure with Saturated water vapour) thus avoiding the inaccuracies of temperature corrections. The transducer is insensitive to the effects of condensation and temperature and avoids the need for individual calibration prior to performing a test.

Significant physical & performance characteristics:

Performance (lung function measurements)

VC, FEV.75, FEV1, FEV3, FEV6, FVC, PEF, FEV.75/VC, FEV.75/FVC, FEV1/VC, FEV1/FVC, FEV3/VC, FEV.75/FEV6, FEV1/FEV6, FEF25 (MEF75), FEF50 (MEF50), FEF75 (MEF25), FEF25-75 (MMEF), FEF50/VC, FEF50/FVC, MVV, FIV1, FIVC, PIF, FIV1/FIVC, FIF25, FIF50, FIF75, FEF50/FIF50, MET2575, FET, TV, ERV, IRV, IC, EVC, IVC, FR, Ti, Te, Ti/Ttot, TV/Ti

Performance (option SpO_2)

SpO_2 (%), Pulse Rate, Recording Time, Valid Sample Duration

Dimensions

255 x 120 x 35mm (MicroLab)
123 x 82 x 23mm (MicroLoop)

Dimensions Transducer

50 x 60 x 90mm

Weight

630g (MicroLab)
191g (MicroLoop)

Weight Dockingstation

124g (MicroLoop)

Transducer type

CareFusion Bidirectional Digital Volume

Display

Colour 1/4 VGA LCD touch screen

Power supply unit

Input 100 to 240V, 50 to 60Hz
Output 12V 2.5A (Class1) (MicroLab)
Output 5V 2.0A (Class1) (MicroLoop)

Battery Pack

Rechargeable NiMH 8.4V 1A-hours (MicroLab)
Rechargeable Lithium Polymer 3.7V 1600mA-hours (MicroLoop)

5.12 Intended Use Statement

The MicroLab / MicroLoop spirometer is intended, for prescription use only, to measure the maximal volume and flow of air that can be moved in and out of a patient's lungs and for pulse oximetry measurements. The system is intended for use with pediatric (4 to 17 years) and adult (18 to 99 years) patients in hospitals, physician offices, laboratories and occupational health testing environments.
The optional Nonin IPOD® Integrated Pulse Oximetry Device is designed to measure pulse rate and oxygen saturation in adult patients. The sensor is designed for use on the fingers of patients weighing more than 30 kilograms, where the finger tissue is between 5 and 21 millimeters.

5.13 Required Components

- MicroLab (with internal printer) or MicroLoop (without internal printer)
- Digital Volume Transducer
- Transducer housing
- USB cable PC / Printer
- Dockingstation – Cradle (only for MicroLoop)
- Instruction for Use
- PSU
- SPCS Software
- Accessories
- Carrying case
- SpO_2 Nonin Ipod oximeter (optional)

5.14 Summary Table of Comparison

A. Pulmonary Function

Pulmonary Function (comparison)		
	MicroLab K031102	**MicroLab / MicroLoop (with SpO_2)**
Indications for Use	The Microlab spirometer is intended, for prescription use only, to measure the maximal volume and flow of air that can be moved in and out of a patient's lungs. The system is intended for use with pediatric (4 to 17 years) and adult (18 to 99 years) patients in hospitals, physician offices, laboratories and occupational health testing environments.	The Microlab / MicroLoop spirometer is intended, for prescription use only, to measure the maximal volume and flow of air that can be moved in and out of a patient's lungs and for pulse oximetry measurements. The system is intended for use with pediatric (4 to 17 years) and adult (18 to 99 years) patients in hospitals, physician offices, laboratories and occupational health testing environments. The optional Nonin IPOD® Integrated Pulse Oximetry Device is designed to measure pulse rate and oxygen saturation in adult patients. The sensor is designed for use on the fingers of patients weighing more than 30 kilograms, where the finger tissue is between 5 and 21 millimeters.

Intended patient population	Pediatric (4 to 17 years) Adult (18 to 99 years)	**similar**
Performance specification (spirometry measurement parameter)	VC, FEV75, FEV1, FEV3, FEV6, FVC, PEF, FEV75/VC, FEV75/FVC, FEV1/VC, FEV1/FVC, FEV3/VC, FEV3/FVC, FEV75/FEV6, FEV1/FEV6, FEF75, FEF50, FEF25, FEF25-75, FEF50/VC, FEF50/FVC, MVV, FIV1, FIVC, PIF, FIV1/FIVC, FIF25, FIF50, FIF75, FEF50/FIF50, MET2575, FET, TV, ERV, IRV, IC, EVC, IVC, FR, Ti, Te, Ti/Ttot, TV/TI	**similar**
Principle of operation	Air flow integration by bi-directional digital volume transducer	**similar**
Material Transducer (breathing path contacting)	Turbine swirl plate (Polycarbonate) Turbine van (Polyester type 427) Turbine tube (Clear Acrylic) Pivot (Nivapoint stainless steel) Turbine Flow deflector (stainless steel) Mouthpiece holder (ABS Plastic)	**similar**
Material Transducer housing (patient skin contacting)	Polyurethane “rubber feel” & black ABS	**similar**
Material device housing	PC/ABS Cycoloy C2950	**similar**
Transducer (type)	Type 36-TDX 1048 CareFusion Bi-Directional Digital Volume	**similar**
Resolution	0,01 liter	**similar**
Accuracy	+/- 3% to ATS Recommendations	**similar**
Volume Range	0.1 – 8 Litres	**similar**
Flow Range	0.2 – 15 Litres/Second	**similar**
Sterilization	Turbine can be disinfected or cleaned	**similar**

5 510(k) Summary

Anatomical sites **(Housing of device and Transducer)**	274 x 134 x 51,5 mm Weight: 820g (with integral thermal printer)	MicroLab: 255 x 120 x 35 mm Weight: 630g (with integral thermal printer) MicroLoop: 123 x 82 x 23 Weight: 191g (without integral thermal printer)
	Handle (transducer): 50 x 60 x 90	**similar**
User input type (no patient contact)	240 x 120 dot LCD Display & 26 Keypad switches	Colour ¼ VGA LCD touch screen Material touch screen foil: PC/ABS Cycoloy C 2950
Energy used (battery)	7,2V NiCad 600 mAh	MicroLab: 8,4V NiMH rechargeable 1000 mAh MicroLoop: 3,7V Li-ion rechargeable 1600 mA
Environ-mental specifi-cations	Operating: 0 to +40 °C 30% to 90% RH Storage: -20 to +70 °C 10% to 90% RH	**similar**
Accessory **(patient skin or mucous membrane contacting)**	VOL2104 Nose Clips (pack of 5) Body material: Polyacetal Pad material: Ethylene Vinyl Acetate PSA1000 Adult Disposable Mouthpiece (material: Polyethylene coated bleached kraft paper) SST1250 One-way Safety Mouthpiece (250 per box) (material: Polyethylene coated bleached kraft paper / Safety wheel & valve: Polystyrene & Rectaleen 8/170) SST1000 One-way Safety Mouthpiece (500 per box) (material: Polyethylene coated bleached kraft paper / Safety wheel & valve: Polystyrene & Rectaleen 8/170) PSA1200 Paediatric Disposable Mouthpiece (material: Polyethylene coated bleached kraft paper) PSA1100 Paediatric adapter (Polypropylene co-polymer, natural Stamylan P512MN10, colour UN0001 white)	**similar**
Software	Spida 5 Software	SPCS Software (Spirometry PC Software)

Summary of technological characteristics compared to the predicate device to the table "A" above:

- There is a new indication for MicroLab / MicroLoop. The Nonin Ipod® Oximeter is used to measure SpO_2 and pulse rate. The technological characteristics are the same as in the predicate devices.
- The housing of the MicoLab / MicroLoop has changed in size and a LCD touchscreen has been used. The material used for the housing did not change compared to the predicate device.
- Both devices use a rechargeable battery as energy source
- The Software of the device changed from the previous Spida 5 software to the SPCS software.

B. Oximetry Function

Oximetry Function (comparison)		
	SpiroPro K092324	**MicroLab / MicroLoop (with SpO_2)**
Oximeter type	Nonin OEM oximeter module (Xpod)	Nonin OEM oximeter module (Ipod)
Principle of operation	Non-invasive pulse and oxygen saturation measurement by red and infrared light emitting technology	**similar**
Intended patient population	Adults and children from 4 years on	Adult patients weighing more than 30 kilograms, where the finger tissue is between 5 and 21 millimeters.
Intended application site	patient's finger	**similar**
Performance specification (SpO_2 parameter)	Accuracy SpO_2 70-100%: - no motion (adults) +/- 2 to +/-3 digits - motion (adults) +/-2 to +/- 3 digits - low perfusion (adults) +/-2 to +/- 3 digits each depending on the sensor used	Accuracy SpO_2 70-100%: - no motion (adults) +/- 2 digits - motion (adults) +/- 3 digits - low perfusion (adults) +/- 3 digits for the Ipod finger sensor
	Heart Rate: - no motion (adults) (18 – 300 BPM) +/-3 digits - motion (adults) (40 – 240 BPM) +/- 5 digits - low perfusion (adults) (40 – 240 BPM) +/- 3 digits	**similar**
Safety Specifications (SpO_2 sensor)	Electrical: (patient isolation) Meets IEC60601-1 dielectric withstand	**similar**
	Mechanical: (ruggedness) shock - IEC 60068-2-27 Vibration IEC 60068-2-6, IEC 60068-2-64	Mechanical: (ruggedness) shock - IEC 60068-2-27 Vibration Mil-standard 810C, method 514-2

	Environment: Operating temperature 0 to +50°C Storage temperature -20 to +50°C Operating humidity 10% to 90% non cond. Storage humidity 10% to 95% non cond.	Environment: Operating temperature -5 to +50°C Storage temperature -40 to +70°C Operating humidity 10% to 95% non cond. Storage humidity 10% to 95% non cond.
Features	Display: LCD display Alarms: no alarms Mode: short term continuous monitoring	**similar**

Summary of technological characteristics compared to the predicate device to the table "B" above:

- The MicroLab / MicroLoop uses the Nonin Ipod whereby the predicate device uses the Nonin Xpod. Both oximeters are interchangeable and thereby the proposed device is substantial equivalent to the predicate device SpiroPro.
- The MicroLab / MicroLoop oximeter is for adult patients - this is a Nonin IPOD sensor specific limitation. The technical limitation for the IPOD oximeter sensor is specified by the original sensor manufacturer Nonin. For the intended patient population the MicroLab / MicroLoop is substantial equivalent to the predicate device SpiroPro.
- The SpO_2 accuracy is the same as for the Nonin Xpod wherby the SpO_2 accuracy depends on the used sensors. Both devices are substantial equivalent.
- The difference in specification is the vibration test which has been done according U.S. Mil-standard instead of IEC and a light changed environment range. The MicroLab / MicroLoop operates as intended in user environments and is substantial equivalent to the predicate SpiroPro.

5.15 Summary of Device Testing

1. Non-clinical tests conducted for determination of substantial equivalence:

Characteristic	Standard/Test	Results Summary
1. Basic Safety	IEC 60601-1	The proposed device passes the applicable tests and standards
2. EMC Compatibility	IEC 60601-1-2	The proposed device passes the applicable tests and standards
3. Risk Management	ISO 14971	The proposed device passes the applicable tests and standards
4. Usability	EN 62366	The proposed device passes the applicable tests and standards
5. Software life cycle	ISO 62304	The proposed device passes the applicable tests and standards
6. Biocompatibility	ISO 10993-1	The proposed device passes the applicable tests and standards
7. ATS / ERS	Standard of lung function testing	The proposed device passes the applicable tests and standards
8. Accuracy Testing	Measurement accuracy for the new oximetry module	The proposed device passes the applicable tests and standards

Summary Discussion of Bench Performance Data
The CareFusion MicroLab / MicroLoop passed all specified test requirements. The validation and verification testing confirmed this device meets user needs and design inputs for pulmonary function and oximetry system. Testing also confirmed physical attributes and device performance meet the requirements of the standards listed in the performance testing summary above. These standards address electrical safety, emc, risk, usability, software life cycle and biocompatibility. All testing which have been performed demonstrate substantial equivalence to the predicate devices.

2. Clinical tests conducted for determination of substantial equivalence and/or of clinical information:

Clinical Performance Data/Information:
Clinical testing was not performed with this device.

3. Conclusion drawn from non-clinical and clinical data:

The Carefusion MicroLab / MicroLoop meets the functional claims and intended use as described in the product labeling. The performance are substantially equivalent to the K031102 MicroLab and K092324 SpiroPro described in the submission.

5.16 Conclusion

Based on the above, CareFusion concludes that the MicroLab / MicroLoop Spirometer is substantially equivalent to the legally marketed predicate devices and as safe as effective as the predicate.